Contents:

8.

Summary of previously published pilot data

Prior to conducting the current RCT we field-tested the VHB for clinical feasibility and proof of concept with 18 veterans at high risk of self-harm being treated at a DBT clinic in the VA Portland HCS[1]. In a cross-over design, patients used both the VHB and a conventional, "physical" hope box over extended periods. Results were extremely encouraging. Patients continued to add content tailored to their individual needs to VHBs on their personal smartphones while away from the clinic, and much preferred the VHB to the conventional hope box. They used the VHB frequently and regularly, found the VHB beneficial and helpful, and said they were likely to use the VHB in the future and would recommend the VHB to peers. In feedback and testimonials, patients were overwhelmingly positive and enthusiastic in describing how they used the VHB to aid coping. Moreover, participating providers were equally complimentary in relating how the VHB helped structure their in-person sessions, and how they saw broad benefits of the VHB across multiple disorders.

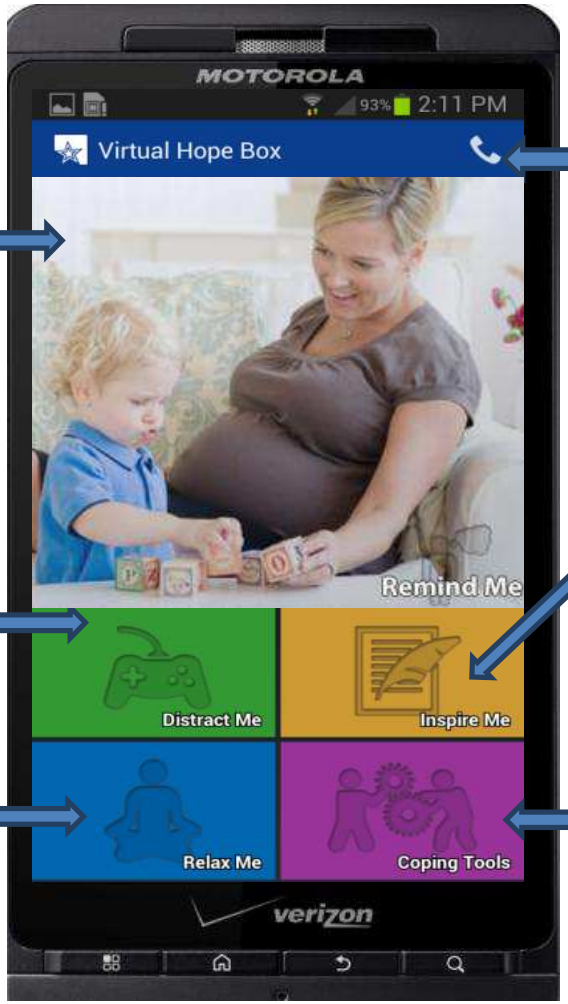
Intervention details

Virtual Hope Box Content: Participants assigned to the VHB condition downloaded and used the VHB app. The VHB contains six primary sections constructed to collectively provide support, comfort, distraction, or relaxation by using audio, video, pictures, games, mindfulness exercises, messages, inspirational quotes, coping statements, and other media content. A provider works with a patient to populate the sections to support the patient's individual needs. The patient then can use the VHB away from the clinic and modify the VHB content in response to changing needs. eFigure 1, below, is an annotated illustration of the VHB home screen.

ETAU Content: Participants assigned to the enhanced TAU control condition received printed materials guiding them in coping with suicidal thoughts[2]. These materials included information about coping

strategies (reminders of reasons for living, reaching out to others, problem-solving and mindfulness techniques, and safety planning) and emergency contact information. We adapted the core of our printed materials for the project and for the VA environment from the British Columbia Ministry of Health's Patient/Family Information Sheet: "Coping with Suicidal Thoughts" [2].

Figure 1: Virtual Hope Box Home Screen



Reminders of Reasons for Living: Focuses the user on cherished memories, reminders in digital media: Photos, videos, recorded messages, music.

User-customized support contacts, hotline info.

Preloaded inspirational quotes can be supplemented or replaced by personal quotes, family aphorisms, biblical phrases, etc.

Distraction tools: Puzzles/word search games taken from user content.

Relaxation tools: controlled breathing tool, progressive muscle relaxation, guided meditations.

Coping Tools:
(a) Coping Cards highlight adaptive thoughts and behaviors when in crisis or managing problematic core beliefs.

(b) Activity Planner used to improve mood by engaging in activities that are meaningful.

Measures details

Primary outcomes (baseline, 3, 6, and 12 weeks):

Coping: For our primary measure of VHB effectiveness in supporting stress coping we administered Chesney's (2006) Coping Self-Efficacy (CSE) instrument.[3] We used two subscales from the instrument which measured perceived ability to 1) stop unpleasant emotions and thoughts, and 2) enlist support from friends and family. Respondents were asked to indicate on a scale ranging from 0 (cannot do at all) to 10 (certain can do) the extent to which they felt they could engage in particular coping strategies when things were not going well or when they were having problems. This measure has shown reliability and validity in depressed samples and can be used to assess change in coping ability over time.[3]

Suicidal ideation: For our longitudinal measure of suicidal ideation we used the first five items of the Beck (1991) 19-item Scale for Suicidal Ideation (BSS).[4] The five-item version of the BSS has been used as a tool for screening the presence or absence of suicidal ideation. [5-8] More recently, the five-item scale has been shown to constitute a legitimate brief measure of change in suicidal thoughts and ideation over time.[9] The BSS has high internal reliability and concurrent validity.[4,10]

Reasons for living: To identify changes in a patient's perceived reasons for living we chose the Brief Reasons for Living Inventory (BRFL).[11] The BRFL contains 12 possible reasons for living if suicide were contemplated, which respondents rate from 1 (not at all important) to 6 (extremely important). The inventory possesses good psychometric properties and is consistent with Linehan's 48-item measure.[12] In implementation of the measure, we inadvertently omitted one item ("purpose in life") and used another item from the 48-item version in its stead. We further deliberately omitted from analysis two items specific to having children which were not relevant for 8 participants in the VHB condition (13.33%) and 11 in the ETAU condition (18.33%). As such, we used 9 of the 12 items of the BRFL.

Secondary outcomes (baseline and 12 weeks)

Interpersonal Needs Questionnaire (INQ)[13]: The INQ assesses indices of thwarted belongingness (the extent to which individuals feel connected to others) and perceived burdensomeness (the extent to which they feel like a burden on the people in their lives), key constructs of Joiner's interpersonal–psychological theory of suicide.[14] Each item was responded to using a 7-point Likert-type response metric ranging from 1 = "not at all true for me" to 7 = "very true for me." These constructs have been shown in interaction to significantly predict suicidal ideation [13] and to have good psychometric properties.[15]

Perceived stress: The *Cohen (1983) Perceived Stress Scale (PSS)*[16] measures perceived stress, indicating how unpredictable, uncontrollable, and overloaded individuals find their lives. Item responses are in a 5-point Likert-type format ranging from 1 = "Never" to 5 = "Very often." We administered the four-item (PSS4) brief version of the PSS to assess relative distress perceived by participants prior to and during the testing phase of the VHB, for use as a covariate measure and to explore whether use of the VHB or control materials, respectively, was related to perceived stress. The PSS4 has shown good factor structure, reliability and predictive validity.[16]

Suicidal ideation intensity: The *Columbia Suicide Severity Rating Scale (C-SSRS)*[17] assesses suicidal ideation intensity and suicide behaviors using a clinician interview format, specifically addressing frequency, duration, controllability, and deterrents of suicidal ideation. The C-SSRS has shown promise in detecting suicide risk based on severity/intensity and in tracking intensity changes in research trials.[17] For the current study we selected two items (aborted attempts, interrupted attempts) from the C-SSRS as secondary measures of suicidal behavior. These items collected the frequency of suicide attempts that were interrupted or aborted by self or by someone or something else prior to the study (lifetime) and at the end of the study (12 weeks of the study). We used the 12 weeks post randomization measure to

compare the groups since we could not estimate a change given the different lengths of time referenced by the two measurement occasions.

Implementation, Process, and other post-testing assessments

Self-reported usage: Participants in both groups were asked at 12 weeks post randomization to report how often they used the study materials. The item used an ordered response format with 0 = "never' and 5 = "more than once/day."

Satisfaction and user experience: We measured satisfaction using two items related to the likelihood of continued use of the study materials after the end of the study and the likelihood of recommending the study materials to others. Both items used a 5-point response metric ranging from 1 = "very unlikely" to 5 "very likely." We also asked participants to indicate how helpful they found the study materials. The response options comprised four categories ranging from 1 = "not at all helpful" to 4 "very helpful." A final item asked participants to rate the ease of use of the study materials with categorical response options ranging from 1 = "very difficult" to 5 "very easy."

Clinician Feedback: We conducted structured interviews with participating clinicians at the trial mid-point, with 23 of the 26 clinicians whose patients were participating in the study, gathering data on their use of the VHB with patients (including barriers to use), and their overall perceptions of patient use, patient benefit, and clinician benefit from using the VHB with their patients. We also explored clinician perceptions of potentially harmful or counter-therapeutic aspects of the VHB.

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Figure 2: Marginal means plot for the CSE: *Stop unpleasant emotions and thoughts* outcome measure, by treatment assignment and time, from the categorical GEE model adjusted for propensity score quintiles.

Coping Self-Efficacy – improved significantly between baseline and 3 weeks (b = 2.69; 95% CI = 0.57, 4.82; B = 0.35) and baseline and 12 weeks (b = 3.14; 95% CI = 0.22, 6.06; B = 0.41) in VHB group compared to ETAU group.

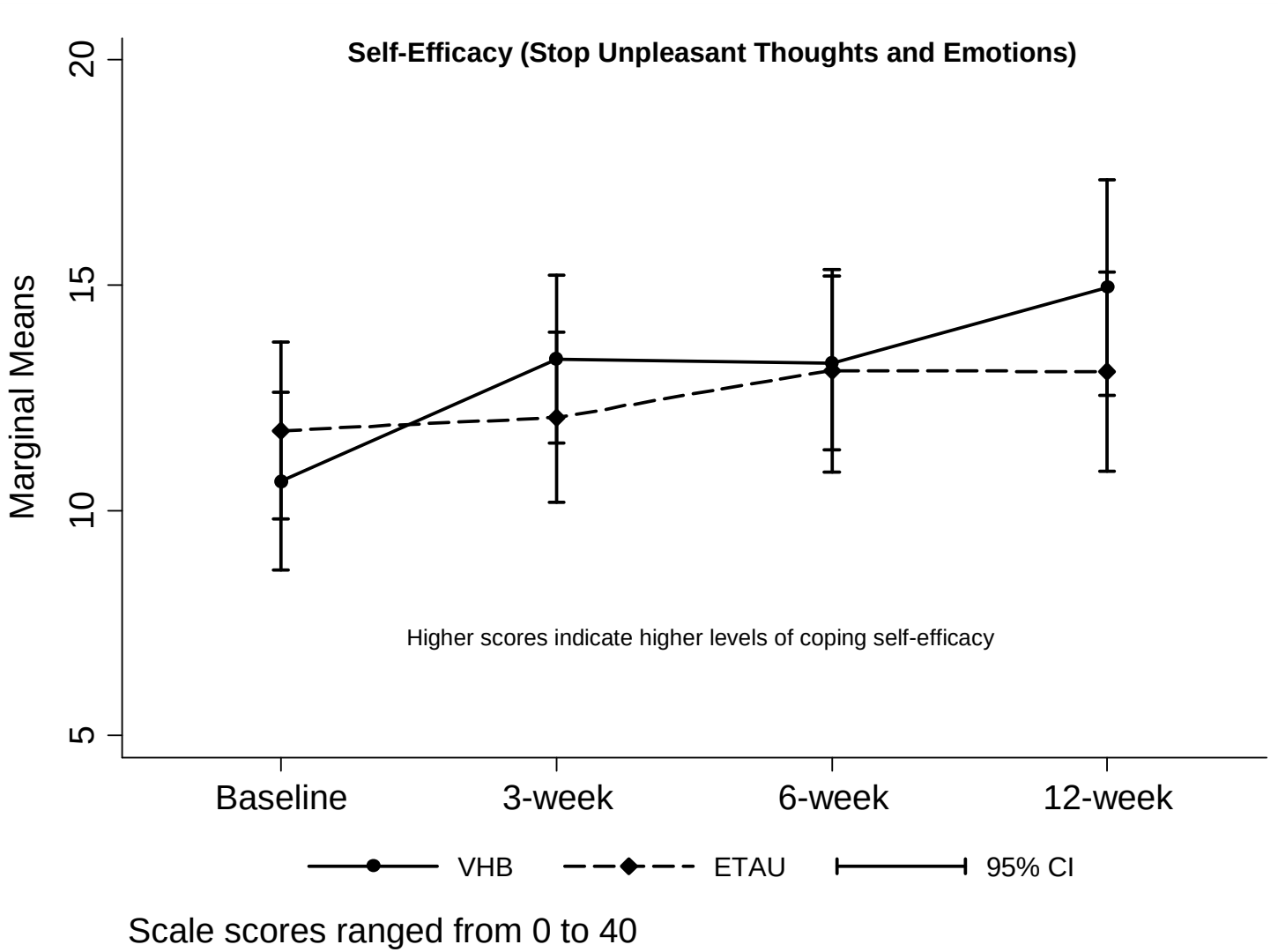

Figure 1.Consort Flow Diagram